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| 09/940,593      | 08/29/2001  | Masaharu Nishida     | NIP-243             | 5020             |

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EXAMINER

GAKH. YELENA G

ART UNIT PAPER NUMBER

1743

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/940,593

Applicant(s)

NISHIDA ET AL.

Examiner

Yelena G. Gakh, Ph.D.

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. RCE filed on 03/04/02, and Amendment filed on 02/04/05 are acknowledged. Claims 1-15 are pending in the application. Claims 13-15 are withdrawn from consideration.

#### *Response to Amendment*

2. Objection to the Drawings is withdrawn in view of the amendment.

#### *Specification*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The specification is objected to as not being written “in such full, clear, concise, and exact terms as to enable any person skilled in the art” to practice the invention in its best mode. For example, it is not clear, what does the expression “parameters on the required reagents ... are to be registered on an inspection item basis” means. What is the “inspection item basis” in the present context? Does it mean that the parameters are registered to be compared for inspection? What are “batch-registered reagent-dependent parameters corresponding to the particular specification of the analytical apparatus” (page 4, lines 23-24)? What type of parameter batches are disclosed? Of different reagents from the same company? Of the same reagent from different companies? The batches defined by the tests? Further, the registration is supposedly conducted for the reagents. But on page 8, lines 13-16 the specification discloses, “the registration is conducted for either the analytical apparatus of the corresponding analytical apparatus manufacturer before the apparatus is delivered, or the analytical apparatus that was delivered to the user”. Therefore, the specification discloses a plurality of reagents, a plurality of reagent manufacturers, and a plurality of analytical apparatus manufacturers. It is hard to understand connections between these pluralities. The disclosure is very confusing. *If the specification was meant to disclose redistributing information about various reagents supplied by different manufacturers so that the information on the same reagent from different*

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*manufacturers were stored in the same place with the similar analytical tests to be performed for this reagent on the analytical instrument for its start-up, it failed to do so.*

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is not clear as to what is a “reagent parameters corresponding to inspection items used in an analytical apparatus”? The term “inspection items” is not disclosed in the specification in clear and definite terms. Therefore, it is not clear, how the reagent parameters can correspond to inspection items, what these reagents are, and which parameters should correspond to the inspection items. Moreover, later the reagent parameters are recited as not corresponding to the inspection items, but rather as characteristics of the inspection items (“a reagent parameter set of one of said inspection items”. Further, it is not clear, what is the difference between reagent parameters stored into a storage medium in the first step and a reagent parameter set of the second step. Also, what are specifications of said reagents? The specification discloses specification for analytical apparatus. The term “specifications of said reagents” is not clear and is not supported by the specification.

Claim 11 is not clear as to how samples are related to reagents, so that their data are measured “based on one of said reagent parameters”. In order to measure these data, the samples should be somehow related to the reagents.

Claim 12 is not clear, as to what is meant by “outputting a series of results”. Does it mean outputting to a remote location? If “outputting” means any way of revealing the data obtained, the step of “measuring” data in claim 11 inherently comprises “outputting” the results in various formats, including graphical representation. It is not clear, what further limitation to the parent claim is supposed to be recited in claim 12.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 10-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 2002/0143725 A1).

Smith discloses “systems, methods and computer program products for determining parameters for chemical synthesis and for supplying the reagents, equipment and/or chemicals synthesized thereby” (Abstract). “As also shown in FIGS. 1E-1G, data entry 110, user query 120 and transactions 130 may be used separately according to embodiments of the present invention. Thus, in FIG. 1E, data entry 110 may be used to populate a database of a plurality of target chemicals, a plurality of corresponding listings of reagent chemicals, a plurality of corresponding listings of equipment and a plurality of corresponding listings of procedures. This database may include three related databases: a chemical database, an equipment database and a supplier

database. As part of data entry, a plurality of target chemicals, a plurality of first pointers to a corresponding plurality of listings of reagent chemicals in the chemical database, a plurality of second pointers to a corresponding plurality of listings of equipment in the equipment database, and a plurality of corresponding listings of procedures are entered into the chemical database. The plurality of listings of equipment are entered into the equipment database, along with a plurality of third pointers to a corresponding plurality of listings of equipment suppliers in the supplier database” (col. 3, [0030]).

While Smith does not specifically disclose parameters on reagents from different suppliers, it would have been obvious for anyone of ordinary skill in the art to include such information in the database, i.e. to register reagents from different suppliers, in order to optimize the choice for their further usage.

### ***Response to Arguments***

11. Applicant's arguments filed 02/04/05 have been fully considered but they are not persuasive. The specification is written in such an unclear and indefinite language that its interpretation is ambiguous. The term “inspection item” is not clear, even while shown on Figure 2. Since “inspection item” is stored on a floppy disk, it may be assumed that this is some sort of a parameter. Which parameter? Is it somehow related to the analytical apparatus? Is it a parameter to be measured on the analytical apparatus? “Inspection item” is a very confusing term and needs to be clarified in the specification. Moreover, it is not clear, what is measured by the analytical apparatus, if a sample is mixed with the reagents. Is the invention related to analysis of the reaction products yielded from a reaction of the reagents and samples? Then this should be clearly disclosed in the specification.

The subject matter of the further discussion of the specification on page 6 of the Remarks is not relevant to the amended claims, since no grouping of reagent parameters according to the “inspection item” is recited in the claims. Also, it is not clear, what “specifications of reagents” recited in the claims are. No specification of reagents is disclosed in the specification. It is rather a specification of the analytical apparatus.

As it was indicated in the previous and the present Office actions, if the specification was meant to disclose redistributing information about various reagents supplied by different manufacturers so that the information on the same reagent from different manufacturers were stored in the same place with the similar analytical tests to be performed for this reagent on the analytical instrument for its start-up, it failed to do so.

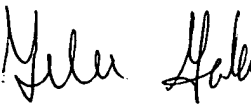
Regarding the prior art: as it is indicated in the previous and present Office actions, while Smith does not specifically indicate parameters on reagents from different suppliers, it would have been obvious for anyone of ordinary skill in the art to include such information in the database, i.e. to register reagents from different suppliers and to group reagents in the lists according to their properties required for performing specific analytical operations at specific analytical instruments, because it allows users to optimize the choice of reagents for further usage.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/7/05

  
YELENA GAKH  
PRIMARY EXAMINER